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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/530,299      | 04/05/2005  | Maxwell Edmund Whisson | 05-296              | 3011             |

34704 7590 01/25/2007  
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| EXAMINER |
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SMITH, PAUL B

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3763

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/25/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/530,299 | <b>Applicant(s)</b><br>WHISSON ET AL. |  |
|                              | <b>Examiner</b><br>Paul B. Smith     | <b>Art Unit</b><br>3763               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 10/23/2006, with respect to Claim 26 have been fully considered and are persuasive. The objection of Claim 26 has been withdrawn.
2. Applicant's arguments filed 10/23/2006, with respect to the Specification have been fully considered and are persuasive. The objection of the Specification has been withdrawn.
3. Applicant's arguments filed 10/23/2006, with respect to the 35 USC § 112 rejection of Claim 26 have been fully considered and are persuasive. The 35 USC § 112 rejection of Claim 26 has been withdrawn.
4. Applicant's arguments filed 10/23/2006 have been fully considered but they are not persuasive.
5. With regards to Claims 16 and 28, Applicant has argued that the disclosure of the Yoon (US 5,584,849) fails to include a needle capable of having fluid flow there through and fixedly mount to the hub such that the needle moves longitudinally together at all times with the hub.

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6. As to the first remark concerning the needle structure, the Applicant's claim language of Claims 16 and 28 recites "a tubular needle". Applicant fails to positively recite language drawn towards fluid communication. Yoon does teach a tubular structure, "Penetrating member 36 has an elongated shaft or body which is at least partially hollow." (See Column 5 Lines 50-55)

7. As to the second remark, the recited claim language "such that the needle and the hub are arranged to move longitudinally together at all times" is considered functional language. The penetrating member of Yoon (US 5,584,849) is not intended to be removed from the hub. Therefore, the penetrating member is considered to be fixedly mounted. Further, Yoon describes a locked extended position in which the penetrating member moves longitudinally with the hub at all times. (See Abstract) Thus, the device disclose by Yoon is functionally capable of meeting all limitations of Claims 16 and 28.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 16-20 and 23-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon ('849).

10. As to Claims 16 and 28-31, Yoon discloses a retractable safety-penetrating instrument comprising a sleeve (42), a needle (36), a hub (24) and a catheter introducer (22). The sleeve is disposed about the needle such that the needle remains at least partially within the sleeve at all times. The needle and sleeve are longitudinally movable relative to each other. The needle is mounted to the hub such that they move together longitudinally. The proximal end of the sleeve is located within the hub and longitudinally movable relative to the hub. Further, a first and a second position are disclosed whereby in said first position the needle extends beyond the distal end of the sleeve and in said second position the sleeve extends beyond the distal end of the needle. The catheter introducer comprises a sheath (26) and a port (28). The needle and sleeve are positioned within the port and sheath such that the needle extends beyond the sheath. Upon insertion the sheath enters the tissue relatively simultaneously as the needle and sleeve. The catheter introducer can be manually held in place in the tissue as the needle and sleeve are removed so that the catheter introducer is left in the tissue for introduction of longer devices. (See Figure 2 and 3)

11. As to Claim 17, the claim further limits the functionality of the apparatus of claim 16 but does not provide any structural limitations. As such, the instrument of Yoon is

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reasonably capable of withdrawing the sleeve from the tissue by application of further longitudinal traction to the hub.

12. As to Claim 18-20, Yoon discloses a laterally extending disc shaped projection (110) from said sleeve located at the proximal end of the sleeve and means of positively engaging (114) said projection to restrain the sleeve in the second position. (See Figure 3)

13. As to Claim 24, the needle of the apparatus of Yoon is inherently in the fluid flow path of the apparatus at all times.

14. As to Claim 25, it is inherent in the apparatus of Yoon that pressure is applied directly to the sleeve from surround tissue upon insertion and retraction from a body.

15. As to Claim 26-27, Yoon teaches a method of using the disclosed apparatus comprising the following steps; piercing tissue with the needle, inserting needle and sleeve relatively simultaneously, applying longitudinal traction to the hub to withdraw the needle and withdrawing the sleeve by further applying longitudinal traction to the hub.

16. Thus it appears that Yoon reasonably appears to teach every element of claims 16-20 and 23-31.

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***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon ('849) in view of Yoon ('176).

20. Yoon ('849) discloses a retractable safety-penetrating instrument comprising a sleeve (42), a needle (36) and a hub (24). The sleeve is disposed about the needle such that the needle remains at least partially within the sleeve at all times. The needle and sleeve are longitudinally movable relative to each other. The needle is mounted to the hub such that they move together longitudinally. The proximal end of the sleeve is located within the hub and longitudinally movable relative to the hub. Further, a first and a second position are disclosed whereby in said first position the needle extends

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beyond the distal end of the sleeve and in said second position the sleeve extends beyond the distal end of the needle. (See Figure 2 and 3)

21. Yoon ('849) discloses a laterally extending disc shaped projection (110) from said sleeve located at the proximal end of the sleeve and means of positively engaging (114) said projection to restrain the sleeve in the second position. (See Figure 3)

22. Yoon ('849) fails to disclose at least one finger arranged to engage with the projection in the second position.

23. Yoon ('176) teaches using a locking finger (86) to engage a substantially flat base (82). (See Figure 3)

24. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Yoon ('849) with the locking finger of Yoon ('176) to provide a means for engaging the projections in a second position and thereby prevent sleeve movement.

### ***Conclusion***

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith  
Examiner  
Art Unit 3763

PBS  
January 19, 2007

  
CATHERINE S. WILLIAMS  
PRIMARY EXAMINER